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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,848	11/29/2001	Howard J. Federoff	12610-011001 / 6-11406-97	4642

26161 7590 06/10/2003

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EXAMINER

SCHMIDT, MARY M

ART UNIT

PAPER NUMBER

1635

13

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,848

Applicant(s)

FEDEROFF ET AL.

Examiner

Mary M. Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-52, drawn to methods of generating a herpesvirus amplicon particle, herpesvirus amplicon particles and cells transformed with herpes amplicon particles, classifiable in class 435, subclass 375.
 - II. Claims 53-55, drawn to methods of treatment, classifiable in class 514, subclass 44.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Invention II is drawn to methods of treatment of a whole organism subject by administration of a therapeutic agent such as an immunomodulatory protein or tumor-specific antigen. Invention I is drawn to methods of generating a herpesvirus amplicon particle and does not have the step of administration to a whole organism for the treatment of cancer.
3. This application contains claims directed to the following patentably distinct species of the claimed invention:

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(1) types of accessory proteins--(a) HSV-1 virion host shutoff protein, (b) HSV-2 virion host shutoff protein, c) HSV-3 virion host shutoff protein, d) bovine herpesvirus 1 virion host shutoff protein, e) bovine herpesvirus 1.1 virion host shutoff protein, f) gallid herpesvirus 1 virion host shutoff protein , g) gallid herpesvirus 2 virion host shutoff protein, h) suid herpesvirus 1 virion host shutoff protein, I) baboon herpesvirus 2 virion host shutoff protein, j) pseudorabies virus virion host shutoff protein, k) cercopithecine herpesvirus 7 virion host shutoff protein, l) meleagrid herpesvirus 1 virion host shutoff protein, m) equine herpesvirus 1 virion host shutoff protein, n) equine herpesvirus 4 virion host shutoff protein;

(2) types of herpesvirus-- (a) Varicell-Zoster virus, (b) pseudorabies virus, c) herpes simplex virus, d) Epstein-Barr virus;

(3) types of VP16 protein (claims 9-10): (a) HSV1 VP16, b) HSV-2 VP16, c) bovine herpesvirus 1 VP16, d) bovine herpesvirus 1.1 VP16, e) gallid herpesvirus 1 VP16, f) gallid herpesvirus 2 VP16, g) meleagrid herpesvirus 1 VP16, h) equine herpesvirus 4 VP16;

(4) types of packaging vectors (claim 11): a) cosmid, b) yeast artificial chromosome, c) bacterial artificial chromosome, d) human artificial chromosome, e) F element plasmid.

(5) types of cosmids: cos6deltaa, cos28, cos14, cos56, cos48deltaa;

(6) type of therapeutic RNA (claim 17): a) antisense, b) RNAi, c) ribozyme;

(7) type of protein (claim 18-35, 53-55): receptor, signaling molecule, transcription factor, growth factor, apoptosis inhibitor, apoptosis promoter, DNA replication factor, enzyme, structural protein, neural protein, histone, immunomodulatory protein, tumor-specific antigen,

*claim 12
- set must comprise all!
not proper to select!*

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antigen of an infectious agent, cytokine, costimulatory molecule, interleukin, interferon, chemokine, B7, CD40L, prostate specific antigen, virus, HIV, gp120, bacterium or parasite, prostate specific antigen, bacterium or parasite, or a specific combination of the above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable for each of groups (1)-(7) above. Currently, (1) claims 1-6, 8-55 are generic for the type of accessory protein; (2) claims 1-2, 5-45, 49, 53-55 are generic for the type of herpesvirus; (3) claims 1-8 and 11-53 are generic for type of VP-16; (4 and 5) claims 1-10, 13-55 are generic for the type of vector; (6) claims 1--16 and 18-55 are generic for the type of therapeutic RNA claimed; (7) claims 1, 37-38 and 45-48 are generic for the type of protein claimed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
June 7, 2003



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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